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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,456	08/21/2002	Israel Raleigh Lurie	Q68463	3880
23373	7590	06/01/2005	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			TOWA, RENE T	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/049,456	LURIE ET AL.
	Examiner Rene Towa	Art Unit 3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 23-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 23-43 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 21 August 2002 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>02/13/2002</u>	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because of the following informalities:

On page 6, line 32, "(16)" should read --(2)--.

Appropriate correction is required.

### ***Claim Objections***

2. Claims 33-35, 40, and 42 are objected to because of the following informalities:

Regarding claims 33 and 34, at line 1, "means to rotate" should read --means for rotating--.

Regarding claim 35, at line 1, "means for collection" should read --means for collecting--.

Regarding claim 40, the claim ends without a period and may be incomplete.

Regarding claim 42, at lines 1-2, "ecto-and/or endo-cervical" should read --at least one of ectocervical or endocervical--.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 25-26, 32, and 37-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites the limitation "the end thereof attached to the plunger" in line 2 of the claim. There is insufficient antecedent basis for this limitation prior to this recitation. It is unclear as to whether there is necessarily an end of the catheter attached to the plunger.

Claim 26 recites the limitation "the end of said catheter remote from the plunger" in lines 1-2 of the claim. There is insufficient antecedent basis for this limitation prior to this recitation. It is unclear as to whether there is necessarily an end of the catheter attached to the plunger.

Referring to claim 32, the use of the alternative language "or other" in line 2 fails to clearly define the metes and bounds of the claim.

Claim 37 recites the limitation "the end" in line 3 of the claim. There is insufficient antecedent basis for this limitation prior to this recitation. It is unclear as to what end of the catheter the recitation refers (i.e. the proximal or distal end of the catheter).

Claim 37 recites the limitation "the opening" in line 3 of the claim. There is insufficient antecedent basis for this limitation prior to this recitation. It is unclear at which opening of the internal cavity the catheter should be located.

Referring to claim 43, Applicant inappropriately attempts to combine two statutory types of invention. The preamble of the claim recites a method however lines 2-9 of the claim define an apparatus. It is suggested that the claim be amended to read --providing a device-- instead of "comprising a device" at line 2 of the claim.

Claim 43 recites the limitation "the end" in line 11 of the claim. There is insufficient antecedent basis for this limitation prior to this recitation. It is unclear as to

what end of the catheter the recitation refers (i.e. the proximal or distal end of the catheter).

Claim 43 recites the limitation "the opening" in line 11 of the claim. There is insufficient antecedent basis for this limitation prior to this recitation.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 23-25, 32, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellard (US Patent No. 5,007,903).

Regarding claim 23, Ellard discloses a device 10 for collection of a fluid sample, comprising a barrel 12 having an opening 37 at one end thereof, a plunger 16 operable axially within the barrel 12; the barrel 12 and the plunger 16 defining a fluid chamber having a volume which varies on axial movement of the plunger 16 within the barrel 12, and a flexible, hollow, elongate catheter 28 extending from the fluid chamber through the opening 37 in the barrel 12, the catheter being in operative engagement with the plunger 16 for axial movement to extend and retract the catheter 28 within respect to the barrel 12 on axial movement of the plunger 16, and said catheter 28 being in fluid communication with the fluid chamber to provide a fluid flow path to and from the fluid chamber through the hollow catheter 28 (see fig. 1).

Regarding claim 24, Ellard discloses a device 10, as described above, wherein the catheter 28 extends into a chamber in the plunger 16 which is in fluid communication with said fluid chamber (see fig. 1).

Regarding claim 25, Ellard discloses a device 10, as described above, wherein the catheter 56 is provided with perforations 60 in the wall thereof at or near the end thereof attached to the plunger for fluid communication with said fluid chamber (see fig. 3).

Regarding claim 32, Ellard discloses a device 10, as described above, further comprising a coil spring device 40 located between the barrel 12 and the plunger 16 of the device 10 (see fig. 2).

Regarding claim 35, Ellard discloses a device 10, as described above, further comprising means for collection (the capsule defined by reference numeral 48 and 51) of a sample of cells or cellular debris, the means being located on said barrel 12 at or adjacent to the opening 47 at one end thereof (see column 3/lines 51-56 and column 4/lines 28-35; see fig. 3).

7. Claims 23, 26, and 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Mahurkar (US Patent No. 5,836,921).

Referring to claim 23, Mahurkar discloses a device for collection of a fluid sample, comprising a barrel 10 having an opening 15 at one end thereof, a plunger 11 operable axially within the barrel 10, the barrel 10 and the plunger 11 defining a fluid chamber having a volume which varies on axial movement of the plunger 11 within the barrel 10, and a flexible, hollow, elongate catheter 13 extending from the fluid chamber

through the opening 15 in the barrel 10, the catheter 13 being in operative engagement with the plunger 11 for axial movement to extend and retract the catheter 13 within respect to the barrel 10 on axial movement of the plunger 11, and the catheter 13 being in fluid communication with the fluid chamber to provide a fluid flow path to and from the fluid chamber through the hollow catheter 13 (see figs. 4 & 5).

Referring to claim 26, Mahurkar discloses a device, as described above, wherein the end of the catheter 13 remote from the plunger 11 is sealed, and the catheter 13 is provided with perforations 26 in the wall thereof at or near the sealed end of the hollow catheter 13 (column 5/lines 1-3).

Referring to claim 33, Mahurkar discloses a device, as described above, further comprising means to rotate the plunger 11 on axial movement of the plunger 11 within the barrel 10 of the device (column 7/lines 48-50).

Referring to claim 34, Mahurkar discloses a device, as described above, wherein the means to rotate is adapted to rotate the plunger from 90° to 360° on full axial movement of the plunger 11 within the barrel 10 (i.e. the plunger 11 rotates according to the curvature of slot 19; see fig. 1).

8. Claims 37-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Gravlee (US Patent No. 3,636,940).

Regarding claim 37, Gravlee discloses a method for collection of a fluid sample from an internal cavity of a mammal, the method comprising the steps of:

(i) locating the end of a flexible, hollow, elongate catheter (i.e. defined by two lumens 21 and 23) at the opening of the internal cavity;

(ii) penetrating the internal cavity by moving the catheter into the cavity while simultaneously passing wash fluid through the hollow catheter (i.e. through the inlet lumen 21) to wash at least a portion of the surface of the internal cavity; and

(iii) subsequently retracting the catheter from the cavity while simultaneously collecting a fluid sample by aspirating the wash fluid through the hollow catheter (i.e. through the outlet lumen 23) (see column 2/lines 71-75; see column 4/lines 112-15; see abstract).

Regarding claim 38, Gravlee discloses a method, as described above, wherein the mammal is a human.

Regarding claim 39, Gravlee discloses a method, as described above, wherein the internal cavity is the uterus 36 of a human female, and the fluid is a uterine wash sample 32 (see figs. 1 & 2; column 2/lines 71-75).

Regarding claim 40, Gravlee discloses a method, as described above, comprising the further step of substantially separating out the fluid sample from the cells and cellular debris (see column 4/lines 12-15 and 67-70).

Regarding claim 41, Gravlee discloses a method, as described above, wherein a sample of cells or cellular debris is simultaneously collected at the opening of the internal cavity (see fig. 2).

Regarding claim 42, Gravlee, discloses a method, as described above, wherein the sample is a sample of ecto- and/or endo-cervical cells (see fig. 2).

Regarding claim 43, Gravlee discloses a method for collection of a fluid sample from an internal cavity of a mammal, comprising a device (21, 22, 23 32, and 33) for collection of a fluid sample, the method comprising the steps of:

- (i) locating the end of a flexible, hollow, elongate catheter (i.e. defined by two lumens 21 and 23) at the opening of the internal cavity;
- (ii) penetrating the internal cavity by moving the catheter into the cavity while simultaneously passing wash fluid through the hollow catheter (i.e. through the inlet lumen 21) to wash at least a portion of the surface of the internal cavity; and
- (iii) subsequently retracting the catheter from the cavity while simultaneously collecting a fluid sample by aspirating the wash fluid through the hollow catheter (i.e. through the outlet lumen 23) (see column 2/lines 71-75; see column 4/lines 112-15; see abstract).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 27-28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellard ('903) in view of Sundberg (US Patent No. 5,494,044).

Ellard discloses a device, as described above, that teaches all the limitations of the claim except that it does not further comprise a filter. Sundberg discloses a syringe with a cell filter 17 located in the barrel 10 in the fluid flow path to and from the fluid

chamber through the hollow catheter 15; the cell filter 17 is adapted to substantially remove cells and cellular debris from a fluid in said fluid flow path (see column 5/lines 34-35, 57-60). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Ellard with a filter similar to that of Sundberg in order to perform in-vivo separation of bodily fluids from cells (i.e. simultaneous collection and filtering operations).

11. Claims 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellard ('903) in view of Sundberg ('044) as applied to claim 27 above, further in view of Schindler et al. (US Patent No. 4,265,249). The device of Ellard as modified by Sundberg discloses all the limitations of the claim except that the filter is not located in the hollow catheter. Schindler et al. disclose a catheter device wherein a filter is positioned in hollow catheter. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Ellard as modified by Sundberg with a filter located in the hollow catheter in order to remove the cells from the body fluid directly inside the body of the patient (column 1/lines 61-64).

12. Claims 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellard ('903) in view of Sundberg ('044) as applied to claim 27 above, further in view of Baidwan et al. (US Patent No. 5,238,003). The device of Ellard as modified by Sundberg discloses all the limitations of the claim except that the filter is not located in the plunger. Baidwan et al. disclose a syringe with a filter located in the plunger (see figs. 1 & 2). It would have been obvious to one of ordinary skill in the art at the time

Applicant's invention was made to provide a device similar to that of Ellard as modified by Sundberg with a filter located in the plunger, which controls the volume of fluid to be collected, so as to maximize the capacity of the fluid chamber of the syringe (i.e. when the filter is located in the barrel, less fluid can be collected with a similar size syringe compared to when the filter is located in the plunger) (see column 1/lines 18-22).

13. Claims 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellard ('903) in view of Parasher (US Patent No. 5,738,109). Ellard discloses a device, as described above, that teaches all the limitations of the claim except that the means for collecting a sample of cells or cellular debris comprises a brush or brush-like device. Parasher discloses a medical catheter with a brush located near a distal end for insertion into a body cavity for collecting a sample of cells or cell debris. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Ellard with a cell collection catheter similar to that of Parasher in order to obtain a large sample of cells that qualifies as a biopsy without the risk of damaging the endo-cervical canal (see Parasher, column 2/lines 17-20 and 31-36).

### ***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 3,626,928 to Barringer et al. discloses a method comprising the steps of: locating the end of a flexible, hollow, elongate catheter at the opening of the internal cavity; penetrating the internal cavity by moving the catheter into the cavity

while simultaneously passing wash fluid through the hollow catheter (i.e. through the inlet lumen 21) to wash at least a portion of the surface of the internal cavity; and subsequently retracting the catheter from the cavity while simultaneously collecting a fluid sample by aspirating the wash fluid through the hollow catheter.

US Patent No. 5,304,150 to Duplan et al. discloses a retractable needle for use with a hypodermic syringe; the catheter engages with the sealing portion of a commercially available hypodermic syringe plunger, allowing it to be withdrawn into the barrel of the syringe after use.

US Patent No. 5,485,853 to Stubbs discloses a syringe apparatus 12 with a hollow catheter 22 for withdrawing fluid or tissue from a patient's body and holds it in a sealed relationship within the barrel of the syringe.

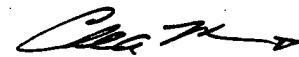
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758.

The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT



CHARLES MARMOR  
PRIMARY EXAMINER